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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,865	12/08/2000	Edwin Oscar Schraa	2578-4257.1US	3138

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EXAMINER

LI, QIAN JANICE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/733,865

Applicant(s)

SCHRAA ET AL.

Examiner

Q. Janice Li

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 October 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ they raise the issue of new matter (see Note below);
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See *Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See *Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 41-46.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

ANNE M. WEHBE, PH.D.
PRIMARY EXAMINER

Continuation of 2. NOTE: The amendment would cause new rejection under 112, 2nd paragraph. The newly presented claims introduced new limitations, and require further search and consideration..

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 41-46 stand rejected under 35 U.S.C. §112, first paragraph for reasons of record and following.

Applicants argue in the after final response that claims are enabled by the specification because prior art of record, such as Bramson et al teach that the presence of neutralizing antibodies do not prevent gene transfer, and the specification has shown that gene transfer to liver and spleen was not completely prevented, and paragraph 87 shown transgene activity was observed in the contralateral tumor remote from the delivery site.

The arguments have been fully considered but they are not persuasive for reasons of record and following.

The claims encompass a method comprising administering an adenovirus lacking a gene of interest followed by administering an adenovirus containing the gene of interest and delivering the gene of interest to any recipient cell via any route of administration using an cross-reactive adenoviruses. However, the specification teaches an intravenous immunization protocol followed by an intratumoral delivering protocol. The specification fails to teach any other means of delivering the gene of interest, yet the claims are not limited to a host having a tumor. Therefore, simply observing a transgene activity in the contralateral tumor remote from the delivery site does not enable the breadth of the claims. It is well known in the art that the tumor cells have abundant blood supply (tumor angiogenesis), and tumor cells metastasis to other organ and tissue in the body, the showing of Example III could be tumor-host specific, because the transgene could be carried to the remote site by transfected migrating tumor cells.

Moreover, the specification fails to teach the transgene activity in any other cell beyond tumor cells via either intratumoral injection or any other means of delivery, particularly, claims require delivering a transgene that is expressed at significant levels in a significant amount of host cells so that a therapeutic effect could be achieved.

In conclusion, the specification fails to support the full scope of the claims.

Claims 41-44, and 46 stand rejected 35 U.S.C. 103(a) as being unpatentable over Bramson et al (Gene Ther 1997;4:1069-76, IDS).

The response after final alleges that the Office has found that the art teaches away from the instant claims in page 3 of paper #16, thus, the instant teaching can not be obvious.

In response, it is noted that the cited sentence in the prior Office action has been taken out of the context, the sentence appeared in a paragraph where other art of record (Parks et al, Kass-Eisler, Mack and Mastrangeli) were cited.

It is noted that other arguments are moot because they are drawn to amended claims, and the amendment has not been entered..